REMARKS

In the Office Action mailed September 20, 2008 the Examiner objected to Claims 1-7 and 9-17, rejected Claims 10-18 under 35 U.S.C. §101, rejected Claims 1-8, 10-17, 19 and 20 under 35 U.S.C. §102(b) as being anticipated by Levenson, et al., Am. J. Roentgenology 156:307-312 (hereinafter, "the Levenson reference"), and rejected Claims 9 and 18 under 35 U.S.C. §103(a) as being obvious in light of the Levenson reference. Each rejection and objection is addressed below.

I. Objection to Claims 1-7 and 9-17

The Examiner stated, "Claims 1 and 10 recite 'echos' where 'echoes' should appear." Claim 1 is amended to correct this misspelling. The canceling of Claim 10 renders this objection moot.

The Examiner stated, "Claims 2-7, 9 and 11-17 fail to further limit the structure of the claimed invention." The canceling of Claims 11-17 renders these objections moot. Regarding Claims 2-7 and 9, Claim 1 is amended such that "data obtained from an MRI device," "a sample," and "software…" are provided as comprising elements of the system. Accordingly, Claims 2-7 and 9 further limit the system.

II. Rejection of Claims 10-18 under 35 U.S.C. §101

The Examiner stated, "Claims 10-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter." Respectfully, the Applicants disagree. However, so as to expedite prosecution without acquiescing with the Examiner's rejections, Claims 10-18 and 20 are canceled rendering these rejections moot. The Applicants reserve the right to prosecute Claims 10-18 and 20, or similar claims, a future date.

III. Rejection of Claims 1-8, 10-17, 19 and 20 under 35 U.S.C. §102(b)

Claims 1-8, 10-17 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by the Levenson reference. In particular, the Examiner stated on page 3 of the Office Action:

Levenson (1991) discloses a computerized method and system of determining the percentage of fat within a sample via MR imaging, including an MRI device (p. 308 col. 1, Subjects and Methods), and software configured to receive data from the MRI device, wherein the data comprise at least one pair of consecutive in-phase and out-phase echoes of a sample collected in magnitude format, wherein the software processes such in-phase and out-phase echoes to calculate and display a percent (fraction) of fat content within the sample (Abstract, p. 309 col. 1, Fig. 2). Levenson (1991) discloses the reference system for use with liver sample data (also constituting a sample from a human abdomen as presently claimed) (Abstract), but it would also be capable of processing abnormal tissue/lesion data, data obtained with a low flip angle of 20 degrees, and data obtained with a high flip angle of 70 degrees. The system of Levenson (1991) is configured to correct for T2* NMR relaxation effects (Abstract).

The Applicants respectfully disagree. However, in order to expedite prosecution while not acquiescing with the Examiner's arguments, the Applicants now amend Claim 1 such that it recites:

> 1.   A system, comprising:
> a)   a sample,
> b)   data obtained from an MRI device, wherein said data comprise at least one pair of consecutive in-phase and out-phase echoes of said sample collected and reconstructed into images in magnitude format, and
> c)   software embodied on a computer readable medium, wherein said software is configured to receive said data obtained from said MRI device, wherein said software is further configured to process said at least one pair of consecutive in-phase and out-phase echoes reconstructed into images in magnitude format, ***wherein said processing comprises calculating the percent of fat content within said sample as between 0 to 100%***, wherein said software is further configured to display said identified fat percentage within said sample. (emphasis added)

Support for amended Claim 1 is located throughout the Specification (see, e.g., Examples II, III and IV and Figures 3-7). The Applicants reserve the right to prosecute previously presented Claim 1, or similar claims, at a future date.

The Levenson reference fails to anticipate all of the elements of Claim 1. As provided in the attached Declaration from Inventor Dr. Thomas Chenevert (hereinafter, "the Chenevert Declaration), the Levenson reference does not teach the step of determining fat content percentage from at least one pair of consecutive in-phase and out-phase echoes of a sample, **where the determined fat content percentage is between 0 to 100%**. Indeed, as described in the Chenevert Declaration, the Levenson reference's approach for determining fat content percentage within a sample is unable to determine whether the fat content is above or below

50%. In particular, the Chenevert Declaration analyzes that the equations described in the

Levenson reference for assessing fat content percentage and concludes:

> In particular, the Levenson reference's use of equation (1) on page
> 309, column 1, is based on well-established expressions to estimate
> fat content given magnitude in-phase and out-phase data, but
> equation (1) is correct only when there are no relaxation effects
> and one knows *a priori* the fat content is below 50%. Equation
> (2), described on page 309, column 1, incorporates factors in the
> event of relaxation effects, but equation (2) and associated text
> does not claim to remedy effects of relaxation.

The Levenson reference readily admits that it is unable to assess fat content percentage without

ambiguity – as clarified in the Chenevert Declaration:

> The Levenson reference describes the inherent limitations
> for removing the ambiguity of determining whether the fat content
> is above or below 50%:

>> Figure 2 also illustrates the second problem
>> associated with equation 1. Because MR imagers
>> typically display only the magnitude of the
>> reconstructed image, **there is an intrinsic
>> ambiguity in applying equation 1 to data**.
>> Although S_{out} accurately reflects the difference in
>> the water and fat signals, **it is not possible to
>> identify whether the fat or the water is the
>> dominant signal**. Mathematically, this means that
>> we do not know the correct sign for S_{out} in equation
>> 1. As a result, for f0 > 0.5, we will in fact be
>> identifying the water fraction, 1 - f0 (shown as the
>> dotted curves in Fig. 2). When this study was done,
>> we did not have the capability of determining the
>> sign of S_{out} from the phase of the image. (page 309)
>> (emphasis added)
>> …
>> In using the f given by equation 1 as "fat fraction,"
>> **we tacitly have assumed that the fat fraction is
>> always less than the water fraction**. On the basis
>> of the biopsy results, it is likely that six of our
>> patients had fat fractions greater than 0.5. As noted,
>> this problem may have reduced our correlation
>> coefficient from .96 to .86 (Fig. 3). A robust
>> application of the method clearly should include a

phase correction scheme (e.g., [3, 10]) so that the
ambiguity is removed. (page 311) (emphasis added)

The Chenevert Declaration concludes that:

> Accordingly, application of the approach described in the
> Levenson reference yields accurate fat content percentage values
> only if true fat content is in the range 0 to about 40%. Contrarily,
> if true fat content is between about 40% to 100%, application of
> the approach described in the Levenson reference yields fat content
> percentage values in gross error.
> ….
> During the course of preparing the present invention, experiments
> were conducted demonstrating determination of fat content
> percentage from at least one pair of consecutive in-phase and out-
> phase echoes of a sample, where the determined fat content
> percentage is between 0 to 100%. Indeed, Examples II, III and IV
> and Figures 3-7 of the present invention demonstrate determination
> of fat content percentage using the system described in Claim 1,
> where the fat content percentage is determined on a scale of 0 to
> 100%. Unlike the Levenson reference, the plots shown in Figures 3
> and 4 are not simulations and represent for the first time
> determination of fat content percentage above 50% derived from
> magnitude data.

As such, the Levenson reference fails to anticipate all of the elements of Claim 1. In particular, as provided in the Chenevert Declaration, the Levenson reference does not teach the step of determining fat content percentage from at least one pair of consecutive in-phase and out-phase echoes of a sample, **where the determined fat content percentage is between 0 to 100%**. The Applicants request the claims be passed into allowance.

IV.   Rejection of Claims 9 and 19 under 35 U.S.C. §103(a)

Claims 9 and 19 were rejected under 35 U.S.C. §103(a) as being anticipated by the Levenson reference. Claim 19 is cancelled, rendering this rejection moot. Claim 9 is dependent upon non-anticipated and non-obvious Claim 1. As discussed in Section III of this Office Action Response, the Levenson reference fails to teach all of the required elements within independent Claim 1. As such, a *prima facie* case of obviousness has not been established. The Applicants request these rejections be withdrawn.

V.   Conclusion

All grounds of rejection of the Office Action of September 30, 2008, have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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